CONFORM-OH

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Sealed Envelope's Red Pill User Guide

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CONFORM-OH

Contents

Version History

Version	Changes/Updates
V1	Document release

CONFORM-OH

1. INTRODUCTION

Sealed Envelope's Red Pill (SE) is the platform for the CONFORM-OH Randomisation System and Clinical Data Management System (CDMS). Users will receive one log in and will be able to select from the different accounts assigned to them as per the delegation log.

SE allows the site to enter data onto a central system and the central trial team at Newcastle Clinical Trials Unit (NCTU) will have access to data as soon as it is entered and saved.

2. LOG IN

Logging in

https://www.sealedenvelope.com/access

When an account is created you will receive an email directly from SE, subject **Invitation to new role.** Please check your junk/spam folder if you are expecting to receive it but have not.

You will be required to change your initial temporary password as your first course of action. You will also be required to accept the invitation to access the trial by clicking on the invitation.
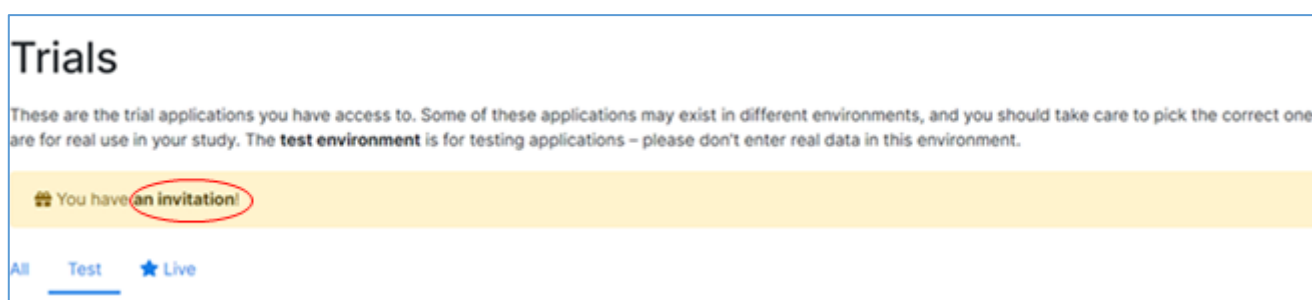
Once you have access to your account, you can add a back-up email address or mobile phone number (in the My Account tab) to allow you to reset your password if you forget it. To reset your password using the back-up email address or mobile number, please use the **Forgot your Password?** function.
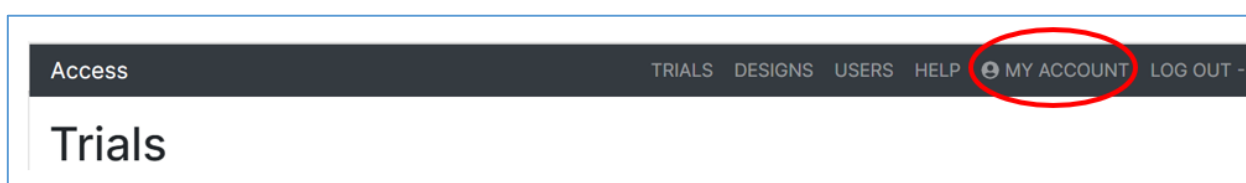
If you have not registered a back-up email address or mobile number, and forgot your password, please email the NCTU Database Support team and someone from the team will reset the password for you.

nctu.database.support@newcastle.ac.uk

If your account is suspended (due to too many unsuccessful attempts at login), you will be notified via email. This suspension will last approximately an hour.

The default 'time out' for SE is 20 minutes; any unsaved data may be lost.

Please DO NOT share your login details. Sharing login details is a violation of GCP.

Training

Prior to being given access to the **Live** system you will be required to perform test actions on the **Test** system. Full instructions will be given when log in is required, see Appendix 1.

Homepage

Once you have logged in you be directed to the SE homepage, from here you will be able to navigate to all trials you have access to (in both Live and Test accounts) and your My Account section.
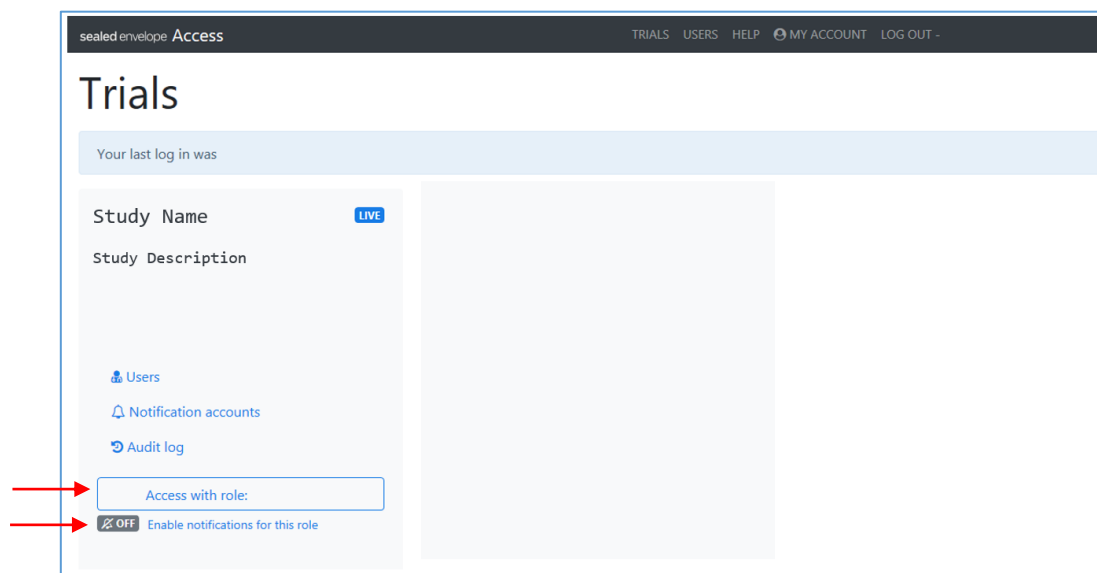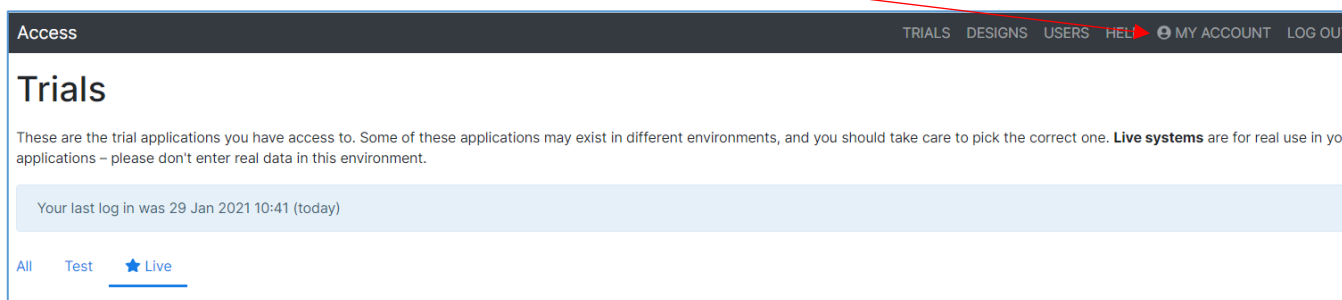
Notification emails are automatically generated by SE. If you do not require these notifications, you can disable them by selecting the **Disable notifications for this role** link under your study login.

Please be aware that if you disable notifications, you will not receive automated system notifications of randomisation.

All trials you have access to on SE will display here. To navigate into a trial, select the appropriate role within the trial section, **Access with role** link, you will be re-directed to your trial's homepage. From this page you can navigate to any applicable section/eCRFs.

For CONFORM-OH site staff with the ability to enter data and randomise patients will have the role **Investigator**.

You can switch between your accounts by selecting the **Trials** tab at the top of the page, this will take you to the SE homepage, you do not need to log out and back in again to change between accounts.

General structure

The general hierarchical structure of the eCRF is as follows:
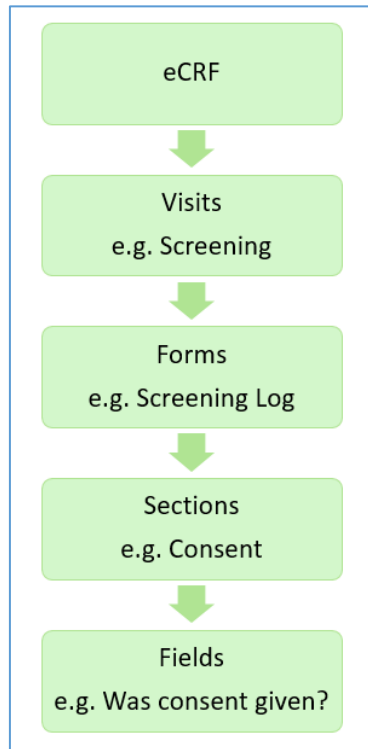
Logging off

To log out please use the **Logout** function at the top right of the screen, do not just close the window.

Help

There are a number of guides provided by SE that cover access, randomising and data entry you may find useful. These can be found in the Help tab or at:

www.sealedenvelope.com/help/access/

www.sealedenvelope.com/help/redpill/

3. ADDING A PATIENT

Select the **Add a subject** tab from the menu bar, this will take you to the Screening log. Screening number is 6 digits starting with site number and then assigned sequentially (110001, 110002 etc). All screened patients should be assigned a unique number. If a patient consents to the trial this will remain their ID number. The database will not allow you to give 2 patients the same number.
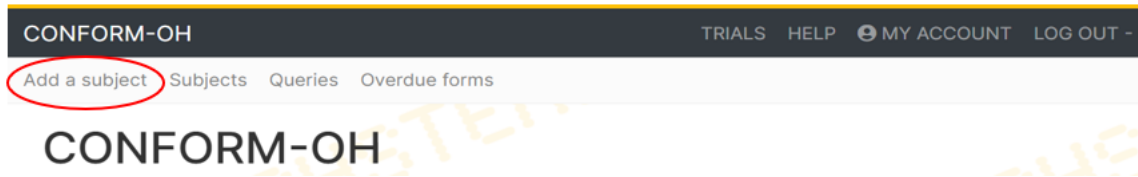
Enter data and **save** the eCRF.

4. RANDOMISATION

To randomise a participant to the CONFORM-OH trial select the participant from the Subject List, then go the Randomisation eCRF and complete the required data. You will be asked to confirm the data by re-entering your password. You will need to complete the Consent and Eligibility eCRFs before the Randomisation eCRF will activate.

From the Subjects detail view on the left side of the screen select **Add**, this will open the Randomisation eCRF.
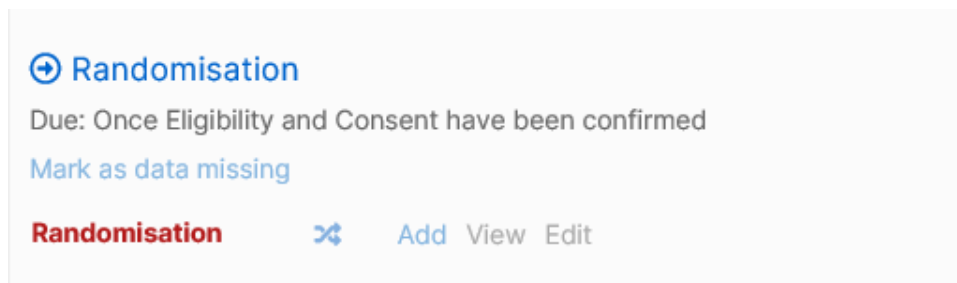
Enter all data on the Randomisation eCRF and select the **Randomise** button at the bottom of the eCRF. The eCRF will reload with the following message at the top. Please take extra care to ensure this is entered correctly as the information on this eCRF will be used to allocate the treatment group.

Scroll to the bottom of the eCRF and complete the **Investigator's declaration**.

Once randomised the system will generate an email and show the treatment arm on screen.
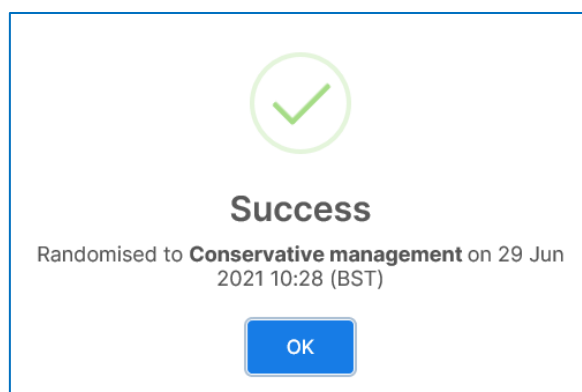

Once a randomisation has been completed, an email notification will be sent to the NCTU trial team and the individual who performed the randomisation, provided that they have their notifications turned on (see section 2. Main Menu). All future applicable visits/eCRFs on SE will now be available for data entry.

5. SUBJECT SCHEDULE

Schedule

You can view all eCRFs for a participant by selecting the **Subjects** tab at the top of the screen, selecting the subject you would like to open in the **Subject Details** section.
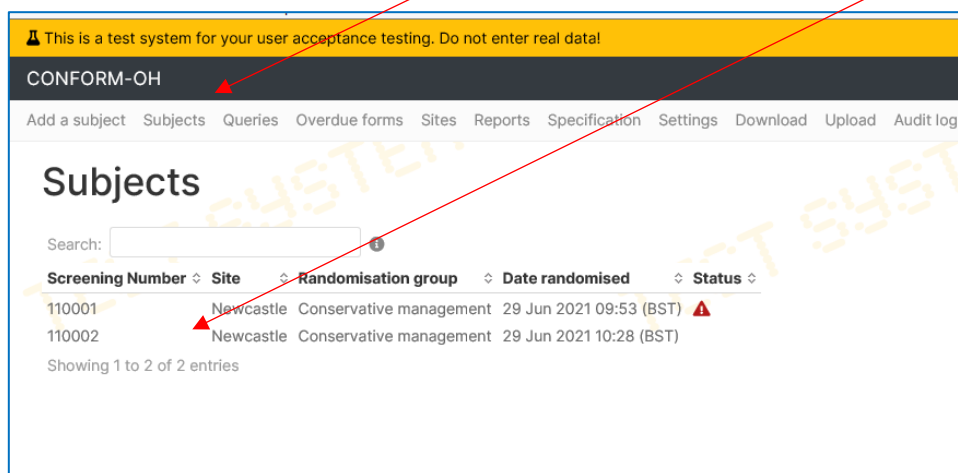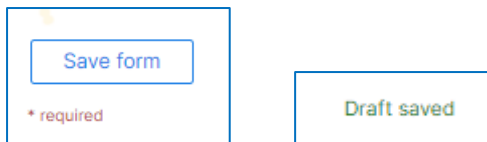

Under each visit, there will be a **Due date**, this is calculated from the date of the Baseline visit. Any overdue visits will be highlighted in Red. Data that is not yet due will be shown in black.
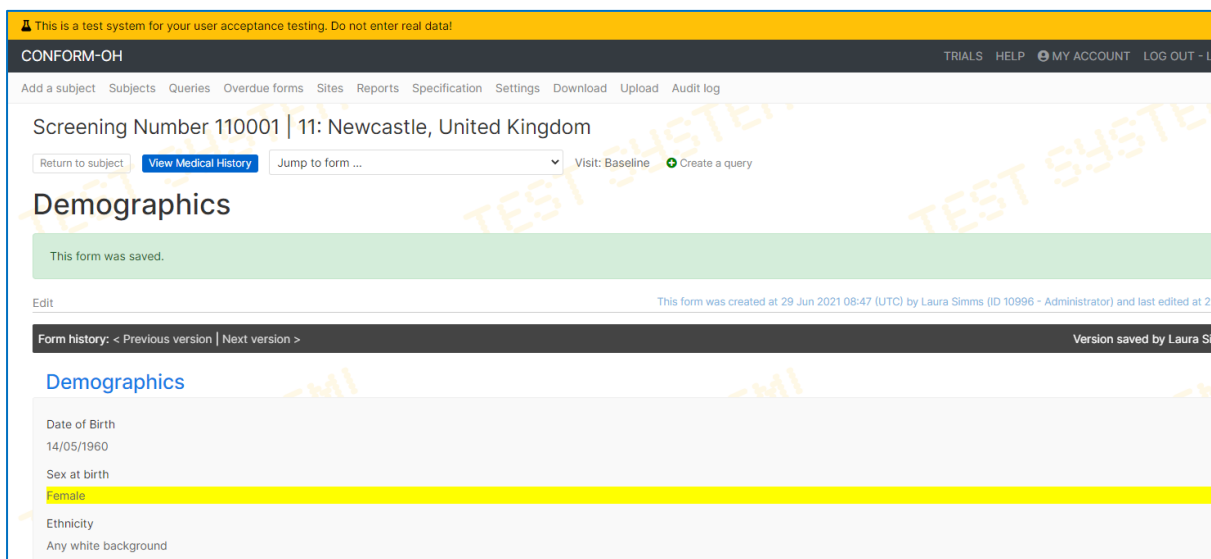
eCRF action

There are three options for an eCRF:

1) Add – enter data and save the page as complete or save as a draft

2) View – view the data that has been saved.

  a. If the form has been edited a history bar will be shown, allowing past versions to be displayed.
  b. Changes to forms will be highlighted in yellow, the exception being repeated sections within forms where no changes will be highlighted.

3) Edit – data can be edited. You can also edit a form by selecting the **Edit this form** link when viewing an eCRF.
  a. Extra fields will be available when editing a form, you must complete the **Reason for edit** box before being allowed to save your change.

eCRF pages to complete

Visits and eCRF will activate based on data entered.

- The **Screening Log** eCRF must be completed before Consent and Eligbility eCRFs are activated
- The **Eligibility and Consent** eCRFs must be completed before the **Randomisation** eCRF is activated.
- All further eCRFs will be activated as required once **Randomisation** has occurred
- The **PregnancyTest** eCRF will be activated for female participants who have been randomised to Conservative management plus fludrocortisone and Conservative management plus midodrine
- The **Bloods** eCRF will be activated for participants who have been randomised to Conservative management plus fludrocortisone and Conservative management plus midodrine

- The **UPDRS** eCRF will be activated for participants with Parkinsons, MSA or Dementia with lewy bodies
- The **LEDD** eCRF will be activated for participants who are taking Levodopa

Visit Schedule

The general structure of the database is as follows:

![CONFORM-OH logo]

Screening log
Due: At any time
Visit date: Date **Screening log** form was entered
Forms
- Screening log

Eligibility
Due: Prior to Randomisation
Visit date: 'Date of completion' (**Eligibility** form)
Forms
- Eligibility

Consent
Due: Prior to Randomisation
Visit date: 'Date participant signed consent form' (**Consent** form)
Forms
- Consent

Randomisation
Due: Once Eligibility and Consent have been confirmed
Visit date: Date of randomisation
Forms
- Randomisation ⤧

Baseline
Due: Once Eligibility and Consent have been confirmed
Visit date: 'Date of baseline visit' (**Baseline Visit** form)
Forms
- Baseline Visit
- Demographics
- Medical History
- UPDRS
- Blood Pressure
- Baseline Culprit Medications
- LEDD
- OHQ
- EQ-5D-5L
- Nottingham Extended ADLs
- Health and Social Service Use Questionnaire
- Pregnancy Test

3 Months
Due: 3 months after 'Date of baseline visit' (**Baseline Visit** form)
Visit date: 'Date of 3 month visit' (**Three Month Visit** form)
Forms
- Three Month Visit
- Treatment Continuation
- Blood Pressure
- Culprit Medications
- LEDD
- OHQ
- EQ-5D-5L
- Nottingham Extended ADLs
- Falls Diary
- Bloods
- Health and Social Service Use Questionnaire
- Review Hospital Appointments

6 Months
Due: 6 months after 'Date of baseline visit' (**Baseline Visit** form)
Visit date: 'Date of 6 month visit' (**Six Month Visit** form)
Forms
- Six Month Visit
- Treatment Continuation
- Blood Pressure
- Culprit Medications
- LEDD
- OHQ
- EQ-5D-5L
- Nottingham Extended ADLs
- Falls Diary
- Bloods
- Health and Social Service Use Questionnaire
- Time and Travel Questionnaire
- Review Hospital Appointments

12 Months
Due: 12 months after 'Date of baseline visit' (**Baseline Visit** form)
Visit date: 'Date of 12 month visit' (**Twelve Month Visit** form)
Forms
- Twelve Month Visit
- Treatment Continuation
- Blood Pressure
- Culprit Medications
- LEDD
- OHQ
- EQ-5D-5L
- Nottingham Extended ADLs
- Falls Diary
- Bloods
- Review Hospital Appointments
- Health and Social Service Use Questionnaire

Adverse Events
Due: At any time
Visit date: *not defined*
Forms
- Adverse Events ⟳

Study Completion
Due: At any time
Visit date: *not defined*
Forms
- Study Completion/Withdrawal

NCTU Data Entry
Due: At any time
Visit date: *not defined*
Forms
- Pregnancy Reporting ⟳
- Pregnancy Tracker ⟳
- SAE Tracking ⟳

The NCTU Data Entry visit is only available to users with an NCTU data entry user account. Staff with Investigator user accounts will not see this visit.
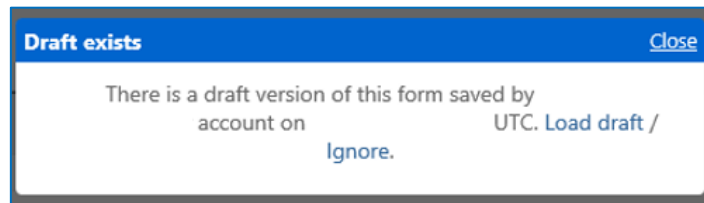
6. DATA ENTRY

Saving Data

There are various options when entering data:

- **Save draft**
  - Once data entry is commenced most forms are auto-saved periodically, with the exception of:
    - Randomisation eCRFs
    - Edits to existing forms
  - A message indicating a draft has been saved is shown periodically at the top right of the form. This allows the user to navigate away from the form and return to later without losing data.
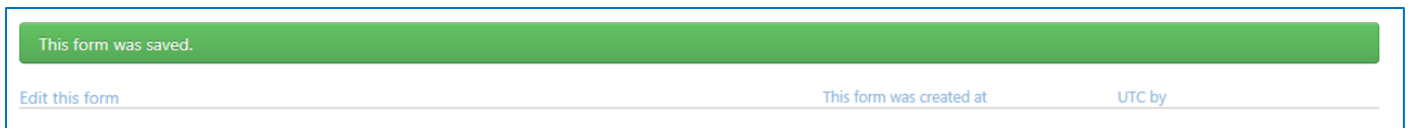
![Draft saved button]

  - When returning to a form that has a saved draft, the user is shown a message and given the option to load the draft data or ignore it. If the draft is ignored and data-entry started again the original data will no longer be available.

CONFORM-OH Database User Guide   V1.0   23/11/2021 based on
Sealed Envelope's Red Pill User Guide Template   Version 1.0   29/JUN/2021
P a g e 11 | 22

CONFORM-OH

- o There is only one draft per eCRF and will be accessible to all users, not just the author of the draft.
- • Save form
  - o Once data entry starts on an eCRF the Save form button will be available at the bottom of the page

Save form

* required
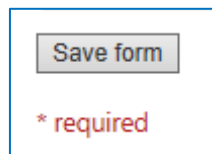
  - o Once the page has been saved a green banner at the top of the page will appear

This form was saved.

Edit this form .... This form was created at .... UTC by
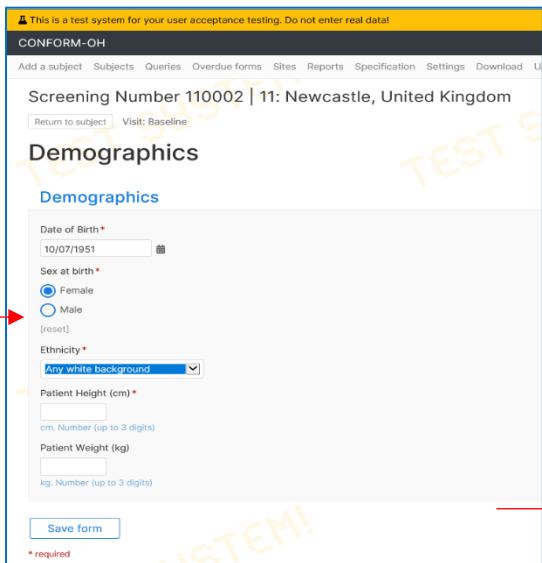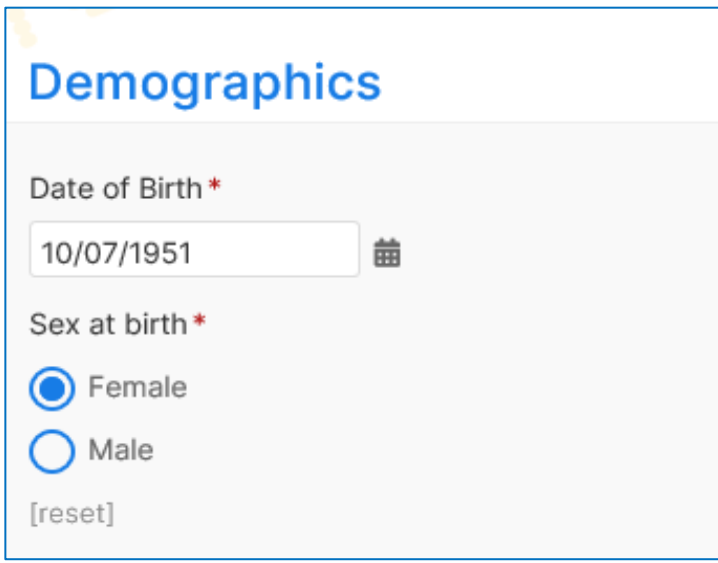
  - o On the Subject details page the eCRF will now have two options available:
    - ▪ View – the eCRF data can be viewed
    - ▪ Edit – the eCRF data can be edited, you will be asked for a reason when you edit a page

Reason for edit*

This field is required.

Save form

* required
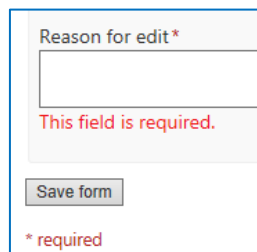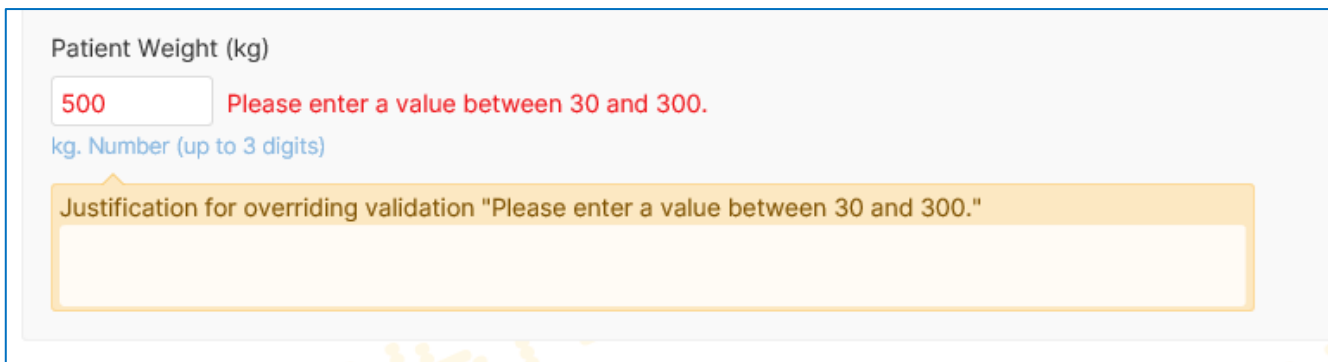
Clearing data

To remove data entered in error from a question, select the answer and press delete. If you have entered data into a radio button/category field in error there is a reset function beneath the field, this will clear all data entered and any subsequent field activation.

Justification boxes

If you enter a piece of information that is unexpected (e.g. Patient Weight) or no data is entered for a field which is mandatory (*) a red justification box will appear. Please check the data that you have/have not entered, if incorrect amend and if correct please document in the justification box why it is different to what is expected.

A justification box must be completed in order to save an eCRF. If you cannot complete the justification box at time of data entry a draft of the eCRF will be saved to allow for completion at a further date.

Warning messages

Validations are carried out at data entry level for some fields. A pop up will appear to alert the user a value maybe incorrect or another message. The user must dismiss the alert before continuing with data entry. Please ensure you review the data entered to prevent future queries being raised on the eCRF.

![CONFORM-OH logo]
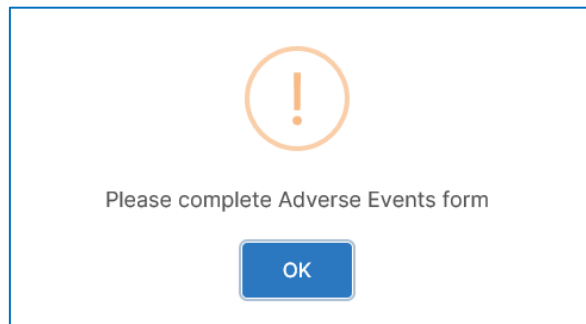
Repeating sections

Some eCRFs have repeated sections, such as the **Falls Diary eCRF**. To enter data you must complete the Falls Diary section and confirm that there have been falls since the last visit select. Then click the **Add Fall Details button** and a sub form will be shown. At the end of data entry you can choose to:

- Add and return to previous form. This will take you back to the eCRF, from here **Save** your data entry.
- Add another. A new sub form will be shown for data entry. At the end of data entry of all the required repeated forms, **save** your data entry.

![CONFORM-OH logo]

Repeating forms

Some forms can have data entered multiple times. They will be listed in the Subject View with a sequence number. Forms that repeat are:

- Adverse Events

Form Completion messages

After a form has been saved, the user might be prompted to complete other forms based on data entered.
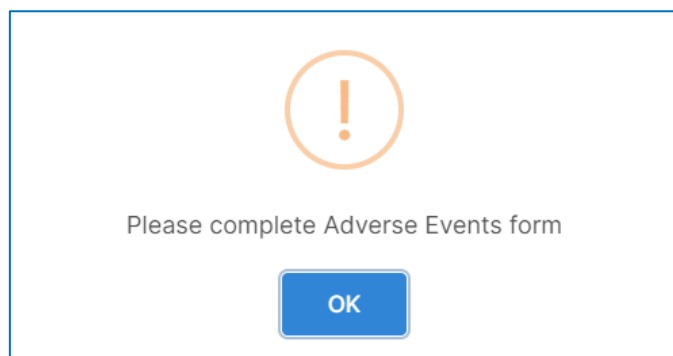
Change in treatment arm

If a participant changes their treatment, please complete the **Treatment Continuation** eCRF in the relevant visit.

Withdrawal/End of Study

If a participant withdraws from CONFORM-OH please complete the **Study Completion/Withdrawal** eCRF, under the **Study Completion** visit of the database.

7. QUERIES

Queries will be raised by the NCTU Trial Team for missing data or discrepancies in the data in addition to automatically generated queries by SE.

Some site users may have the ability to raise queries. Please do not raise queries to use as notes or comments If you have any queries please contact the trial DBM/DM or TM.

Site staff with **Investigator** access should check for raised queries 🔶 regularly, respond to queries and amend data if required. Note that, not all queries will require data to be amended.

Opening and responding to queries

When a query is issued it will be flagged by an amber question mark 🔶 . You can view queries on one of two ways:

1. **Subjects** tab

- A 🔶 symbol will appear beside a subject entry if there are any queries for this participant.
- Select the participant to show their details in the right-hand side of the screen.
- Locate the 🔶 and **View** the eCRF.
- Open queries will be listed below the eCRF header.

- Click on the query to open full details.
- Reply to the query in the **Message box** then select **Add message**. Please remember to edit the eCRF if data needs amending in addition to responding to the query.
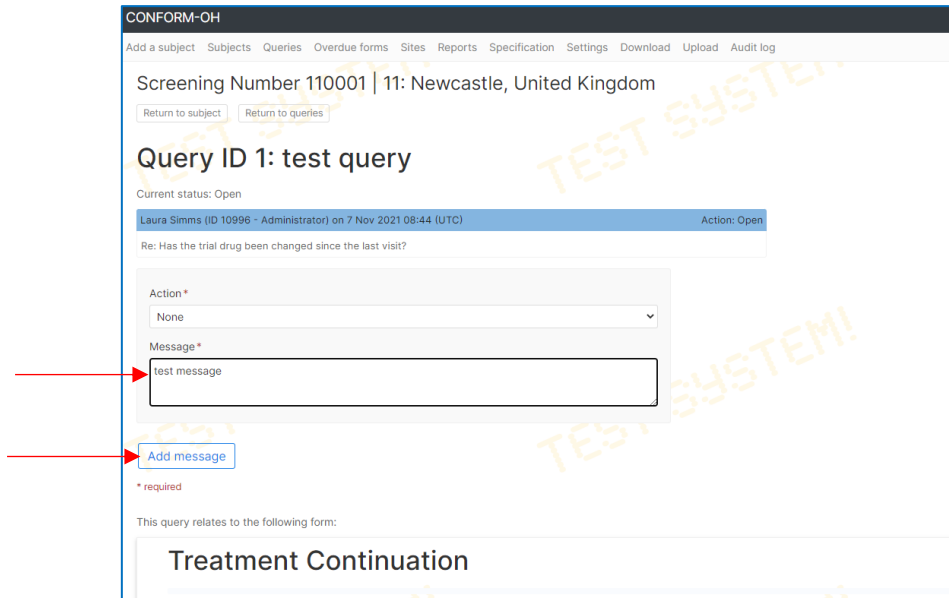
2. **Queries** tab
- A list of all open queries for all participants will be show here.
- Select the query you would like to respond to, the query will appear in the top right-hand corner of the screen.
- Selecting **Edit query** will take you directly to the query message box as detailed above.
- Selecting **View Subject** will take you to the Subject Detail view, as detailed above.
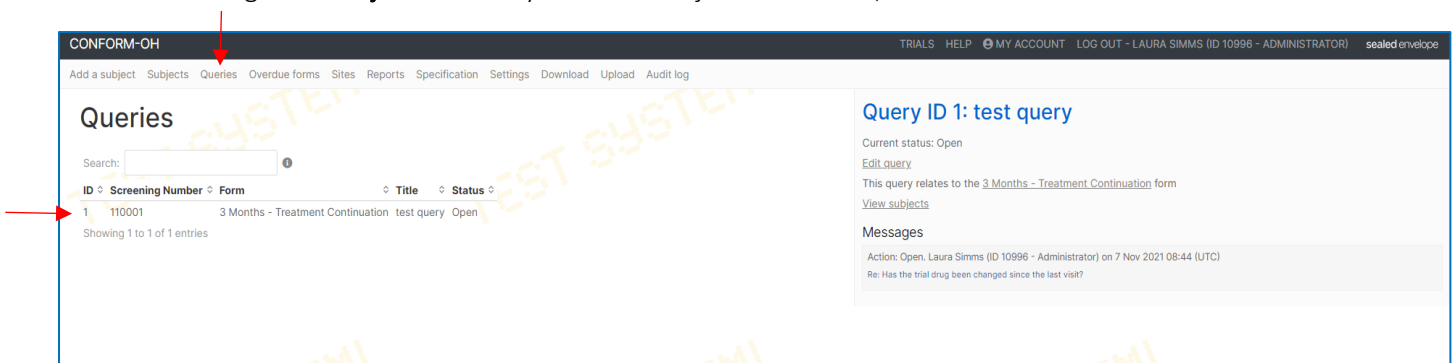
Closing queries

Once queries have been responded to NCTU Trial Team will review the query response and associated data. If the data is consistent the query will be closed, if the data is inconsistent the query will be re-raised.
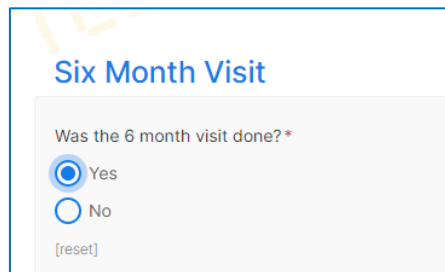
8. TIPS

Form Navigation

- Forms can be navigated through with the tab key

o Enter data through typing
o Use the space key to highlight a radio button

Six Month Visit
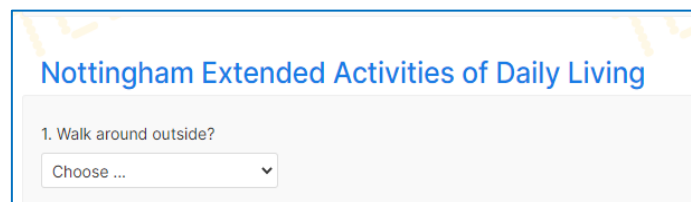
Was the 6 month visit done? *

( ) Yes

( ) No

[reset]

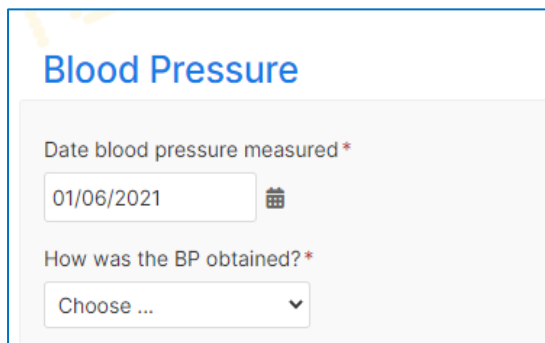o Use the arrow keys to select a drop-down answer

Nottingham Extended Activities of Daily Living

1. Walk around outside?

Choose ...   ▼

- Fields with a red asterisk * are mandatory fields and are required in order for you to save the page.
  o If you do not have the data at point of data entry you can save the draft and come back to data entry at another time.
  o If the data was not completed you must detail this in the justification in order to save the page.
  o Some data fields are mandatory but are conditional on previous data entry and will not have a mandatory indicator. A justification box will appear if you try to save the eCRF without entering data in these fields.
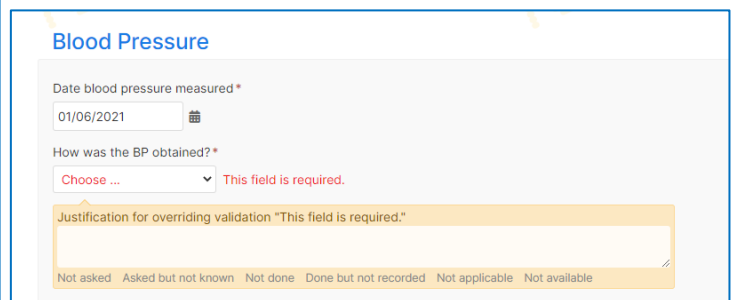
Blood Pressure

Date blood pressure measured *

01/06/2021

How was the BP obtained? *

Choose ...   ▼

Blood Pressure

Date blood pressure measured *

01/06/2021

How was the BP obtained? *

Choose ...   ▼   This field is required.

Justification for overriding validation "This field is required."

Not asked   Asked but not known   Not done   Done but not recorded   Not applicable   Not available

- Once data has been saved on an eCRF you can navigate to another eCRF by using the tabs at the top of the eCRF.
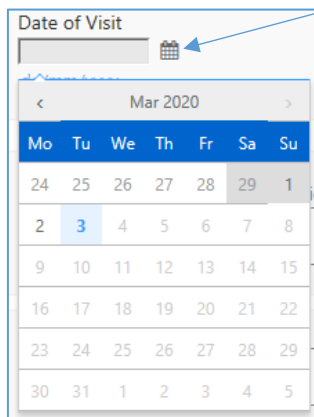
To navigate back to the participant details use the Participants tab and select the participant you require from the list of participants.
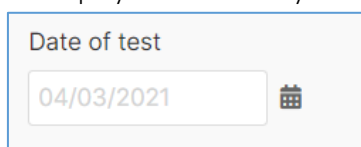
Dates and Time

- Dates can be entered as text (e.g. 01/01/2020) or you can use the calendar function (you will not be able to enter dates in the future).
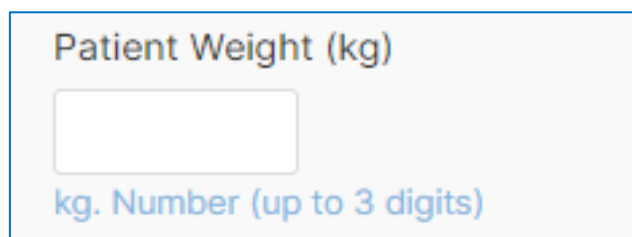

- Date fields will have today's date in light grey text to show the format of the date required, you are still required to enter the date even if the date displayed is the date you would like enter.

Field formats

Please check the format of the data you are entering.

- Results will have the format below the field in blue.

- Some fields are only required if a previous field has been completed with a certain answer, e.g. you must enter *Yes* for *Was the baseline visit done*? to enter Date of baseline visit. Conversely, some fields are locked for data entry, please check your answers to preceding fields.

Missing data

Please do not leave blank fields.

- If the data is required a justification box must be completed in order for the page to be saved, e.g. How was the BP obtained
- If an entire visit data is not available please use the Mark as data missing function under the visit header.

o   The wording under the visit header will now read *marked as missing* and all eCRFs with no data in are now locked

Form Validation

During the course of the trial the Trial Manager and Data Manager will mark eCRFs as 'Validated' once they have been checked or monitored. This is indicated by a green tick next to the eCRF name:

If you need to go back to edit a validated form you will get a warning message:

CONFORM-OH

⊖ This operation is not permitted

This form has been validated and can not be edited. Please ask a monitor to remove the validated status if you need to edit this form.

Go back

You can still update the data if needed, you will need to contact NCTU so we can unlock the page.

9. CONTACTS

If you have any problems, please contact the Newcastle CTU database team on the email below:

nctu.database.support@newcastle.ac.uk

Appendix 1. Training

Prior to being given access to the **Live** system you will be required to perform test actions on the **Test** system. For each step you will be instructed to a task for a specific patient/participant denoted below by XXX.

- Data entry and Randomisation access
  - Please **randomise** patient XXX into the CONFORM-OH trial. Please note that the Eligibility and Consent eCRFs must be completed prior to a randomisation being performed.

- Access to the **Live** system will be given upon providing an updated delegation log and training log.